PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P70357WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB98/00652	03/03/1998	30/04/1997
International Patent Classification (IPC) or national classification and IPC A61B17/12		
Applicant BRADFORD HOSPITALS NHS TRUST et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 18 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☐ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19/11/1998	10.08.99
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. (+49-89) 2399-0 Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer Dhervé, G Telephone No. (+49-89) 2399 2415

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB98/00652

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-13	as received on	26/06/1999	with letter of	23/06/1999

Claims, No.:

1-25	as received on	26/06/1999	with letter of	23/06/1999

Drawings, sheets:

1/3	as originally filed			
2/3,3/3	as received on	26/06/1999	with letter of	23/06/1999

2. The amendments have resulted in the cancellation of:

☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 22-25.

because:

☒ the said international application, or the said claims Nos. 22-24 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 25 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

In claim 25, the applicant defines an obturator with only reference to the drawings. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here because an obturator can be defined by its structural features (see also the PCT Guidelines, PCT/GL/3-III,4.10). For this reason, claim 25 as a whole does not meet the requirement of Article 6 PCT and, therefore, no international preliminary examination can be carried out on **claim 25**.

No international preliminary examination is carried out on **claims 22-24** because they relates to a method of treatment of emphysema which involves a treatment of the living body by surgery (see Article 34(4)(i) PCT and Rule 67(1)(iv) PCT).

VII. Certain defects in the international application

In the description, page 13, line 27, reference sign 302 should have been corrected into 304.

VIII. Certain observations on the international application

Amended claim 1 is worded so as to fall into another category than the originally filed claim 1, that is a claim to the use of elements, a blocking and a securing element, in the manufacture of a medical device, an obturator, for use in a medical treatment ("Swiss-style" of claim), whereas the original claim 1 was concerned with the medical device itself. No provision is made in the PCT on the allow ability of such an amendment or claim style, consequently the following observation is made based on the European patent convention and guidelines.
This Swiss-style is allowable for claims which refer to a "substance" or "composition" (see the EPC Guidelines C-IV,4.2) which is not the case in the present claim 1 since it refers to an obturator. The surgical and therapeutic use of an obturator cannot be considered as analogous to a therapeutic use of a substance/composition since the obturator is not consumed in the application, its non-decomposition being sine qua non

to its aim, the obturation. Therefore, the International Preliminary Examining Authority cannot establish an opinion with regard to novelty, inventive step and industrial applicability of the aforementioned **independent claim 1 and its dependent claims 2-21.**

OCCLUSION DEVICE

The present invention relates to a device useful in the treatment of emphysema and other diseases or disorders of the human or animal lung.

Emphysema is a disease of the lung caused primarily by prolonged smoking, although not exclusively thereby. It is an unrelentless, intractable and debilitating process. Emphysema is defined as an abnormal permanent enlargement of the air spaces distal to the terminal bronchioles, accompanied by destruction of their walls without obvious fibrosis. In this context, destruction means non-uniformity in the pattern of respiratory airspace enlargement; orderly appearance of the acinus is disturbed and may be lost.

Emphysema causes a physiological loss of lung elastic recoil, which decreases expiratory airflow by loss of driving pressure and premature airway closure from reduced airway traction. The effect of this is that the alveoli become hyper-inflated without there being any real exchange of air with the outside. Therefore the patient begins to feel starved of oxygen and so attempts to breathe more deeply. In breathing more deeply, the effects are exacerbated.

Not only are those individual alveoli which have a block in their respective bronchial tubules affected, but also neighbouring alveoli, perhaps in other regions of the lung, which may otherwise be perfectly serviceable, become affected because the hyper-inflated alveoli pressurise neighbouring alveoli and prevent them from expanding fully. There is, of course, a relatively fixed "exchange" volume of an individual's lung, that is to say, the difference between the expanded volume and the deflated volume. Emphysema reduces the exchange volume because undeflated

alveoli occupy that space. Consequently, the only recourse available to the patient is to increase the expanded volume, thereby resulting in the barrel chest symptomatic of emphysema sufferers.

The major therapeutic modalities currently available consist of bronchodilator and anti-inflammatory drugs, directed at decreasing airway resistance, and antibiotics to treat acute and chronic infection. Supplemental oxygen therapy for the hypoxaemic patient improves exercise performance and improves survival in patients with cor pulmonale. Despite all available medical therapies, the course of the disease is one of progressive limitation, increasing dyspnoea and significant increase in overall mortality.

It has long been realised that full lung volume is more than enough for survival in most circumstances and that a person can survive quite satisfactorily with only one lung, for example. Heterogenous distribution of emphysema, together with the lack of pulmonary blood flow to those areas have made lung volume reduction surgery a logical option. Removal of parts of the lung affected by emphysema permits unaffected areas to become operative again and so enable a better quality of life for the patient. Clearly, however, such invasive procedures are of a very serious nature and some patients will not, in any event, be in a sufficiently strong condition to accept the trauma of such procedures. Primarily, the basic relief for emphysema sufferers is inactivity, on the one hand, and breathing pure oxygen, on the other.

Emphysema is a distressing condition affecting a relatively large proportion of the population, and a more effective and less traumatic treatment is required.

On a different matter, other lung conditions sometimes lead to bleeding into the lung. A patient having this

condition feels movement of the blood caused by airflow in the lung during breathing, and perceives the blood as a foreign body and irritant. The patient coughs in an attempt to dislodge the perceived foreign body. Coughing blood, of course, is sometimes the first warning of a more serious disease or condition, but once that is realised, there is no benefit in such bleeding. Moreover, in such conditions where the lung might heal itself and subsequently stop bleeding, or indeed simply where the bleeding needs to be confined, the coughing reaction, which is almost impossible to resist, does not help the situation at all, and merely spreads the blood to other areas of the lung.

US-A-5382261 discloses a vessel occluder for providing permanent occlusion of a vessel in a person by use of a flexible closure member attached to at least one radially expandable stent. The occluder does not have barbs or anchors or a stent.

DE-U-9205797 discloses a self expanding 'meshbasket' for the occlusion of human hollow organs. The invention is directed to female contraceptive devices and addresses the problem of remaining in place. The device may also find application in embolism therapy and vascular occlusion.

WO-A-9532018 discloses a body passageway closure for use in the occlusion of various passageways within the body, with particular application for the occlusion of blood vessels.

Therefore it is an object of the present invention to provide a method of treatment of certain lung conditions or diseases and to provide a device for such treatment.

In accordance with a first aspect of the present invention there is provided a method of treatment of emphysema or other lung conditions or diseases, the method comprising

placing an obturator in a bronchial tube or tubule so as to seal the tube or tubule against the passage of fluid past the obturator.

In the case of emphysema, and by the simple expedient of inserting an obturator in a bronchial tube, a section of a lung can be isolated so that no air can be drawn into it. Thereafter, the isolated part deflates in time as the air remaining in it becomes absorbed, and so that part of the lung stops affecting other areas of the lungs, which can thus perform normally. Such a procedure is relatively simple, requiring only a delivery device for the obturator, which device is inserted through the mouth and airway of the patient until the proposed placement site is reached, whereupon the device is activated to release the obturator from the device.

In the case of bleeding into the lung, an obturator stops the flow of blood. The lung is tamponated by the obturator and blood merely collects in the isolated part of the lung and ultimately, if the bleeding stops, will be reabsorbed. Alternatively, in the case of some, perhaps terminal, conditions such as some lung cancers, it at least provides temporary relief for the patient.

In accordance with a second aspect of the invention there is provided the use of a blocking element and a securing element in the manufacture of an obturator for use in the treatment of a lung condition in a human or animal by blocking a bronchial tube or tubule. The condition may be emphysema.

Preferably the two elements are separate components, the blocking element serving to seal the tube or tubule against the passage of fluid past the obturator when the obturator is disposed in a bronchial tube or tubule, and the securing element serving to retain the blocking element in position in the tube or tubule.

The blocking element preferably comprises a substantially cylindrical plug of biocompatible material. The plug may comprise resiliently deformable closed-cell foamed plastics material, such as PVC, so that it may be compressed to facilitate insertion into the tube or tubule and thereafter expand to fill the cross-section of the tube or tubule.

It is known to employ stents in medical fields to expand and support collapsed blood vessels, and indeed bronchial tubes. A stent is a compressible framework which, when inserted into a vessel and released, expands and, within the limits of its expansion, supports and possibly expands the walls of the vessel.

Preferably, the securing element comprises a stent. The stent may have barbs to engage and retain the blocking element. The stent preferably also has anchors to retain the stent in a bronchial tube or tubule.

In one embodiment, the stent comprises a crown of surgical quality steel wire legs in zig-zag formation. Said barbs and anchors may depend from points of the crown. Preferably the crown is closed in its circumference, although this is not essential.

In another embodiment, the stent comprises a dome of surgical quality steel wire legs. Said barbs and anchors may be formed on the ends of said legs.

It is known in medical fields to block blood vessels, for example where a genetic or other defect has resulted in a hole which needs blocking, or, for example, in the case of babies whose aortic to pulmonary artery connection has not closed following birth, a condition known as patent ductus arteriosus. In the case of holes, it is well known to employ an "umbrella", where a diaphragm of material forms the seal against the blood vessel wall, the handle of the

umbrella serving to keep the diaphragm across the vessel. In the case of babies, it has also been known to employ a plug of PVC foam to treat patent ductus arteriosus, the plug encouraging clotting.

However, in the case of bronchial tubes and tubules a diaphragm seal has not been used yet, although its application cannot be entirely ruled out. For example, an umbrella device with a larger surface area of contact with the bronchial mucosa might be as effective.

In blood vessels a complete seal is seldom required because any leak soon blocks by the formation of a clot; something that would not happen in an airway of a lung. Secondly, airways are not always absolutely circular in section, so a circular diaphragm may not always make a good seal, at least around some parts of the circumference, unless it has capacity to expand in all radial directions and has a large contact area.

However, a complete seal is an absolute requirement of the present invention (at least over the period of a single breath), because without it, air can leak past during inhalation and pressurise the lung in just the same way, and perhaps even to a greater extent. More importantly, however, a patient with such an obturator in place can only feel its presence if there is movement of air around it to stimulate adjacent nerve endings. Once a patient can feel the obturator, there will be irresistible compulsion to cough which, if done excessively, may be sufficient to dislodge the obturator.

Thus it has been found that a very effective seal is achieved by the use of said cylindrical plug of foamed PVC (of the type commonly employed as earplugs). The effectiveness of this arrangement is probably due to the fact that any leakage path has to be a long one and there are thus numerous opportunities for it to close and seal

about at least one closed circuit around the plug. Another reason is that a plug can mould itself to the shape of the tube or tubule, which is itself unlikely to be cylindrical, or, indeed, circular in cross-section.

Preferably, the method of the present invention employs an obturator of the type defined above.

The delivery device preferably comprises a delivery tube in which the obturator is received in a compressed state at a distal end thereof, a guide tube, which is capable of following a possibly tortuous path under the guidance of a surgeon from entry into the mouth of a patient, down the patient's trachea and one bronchus to a proposed delivery site in a bronchial tube or tubule, and which has a passage to receive the delivery tube therealong, and release means to eject the obturator from the delivery tube and guide tube.

The obturator needs to slide in the delivery tube during ejection and the stent provides a low friction surface of the obturator to facilitate such ejection.

It is feasible that the blocking and securing elements may be integrally formed from plastics material, and wherein the securing element comprises adhered or fused anchor elements on the blocking element.

It is also feasible that the securing element may comprise a memory metal which is released to its normal expanded shape by a physical parameter, for example, the passage of an electric current therethrough, once it has been inserted at the proposed location. Otherwise it is in the same form as the above described steel stent which relies on resilience for its expansion. The advantage of a memory metal device is that it requires no compression during insertion so that the delivery tube of the delivery device may be replaced by a simple guide rod to which it is

connected.

The invention will be better understood from the following description of particular embodiments given as non-limiting examples. The description refers to the accompanying drawings, in which :-

Figure 1 shows a section through the human chest indicating the location of bronchial obturators in the lungs;

Figure 2 shows a bronchial obturator complete with delivery system;

Figures 3a b and c show in perspective two embodiments of an obturator according to the present invention, that of Figure 3a having a crown stent, and that of Figure 3b having a dome stent, Figure 3c being a crown stent in an open configuration prior to rolling and, optionally, welding into a ring as in Figure 3a;

Figures 4a and b show an internal barb and external anchor respectively;

Figure 5 is a perspective view of another embodiment of obturator in accordance with the present invention; and,

Figure 6 is a perspective view of yet another embodiment of obturator also in accordance with the present invention.

In Figure 1 of the drawings, a human chest cavity 10 includes a pair of lungs 12 which each comprise upper and lower lobes 14,16. A trachea 18 branches into two bronchi 20, which further branch into bronchial tubes 22 and segmental bronchi 24. The bronchi 24, after further branching, terminate in alveoli 26.

In the majority of patients suffering from emphysema, it frequently effects mainly the upper lobes 14 of the lungs, leaving the lower lobes 16 unaffected, or at least less affected. However, if no treatment is given to a patient, the expansion effect of the upper lobes as the condition

develops presses on the lower lobes and reduces their capacity to perform efficiently. Lower lobe emphysema does occur in some patients, and in which event it is then the upper lobes which are compressed.

Thus the present invention suggests placing an obturator 50 in a bronchial tube or tubule to isolate the region of the lung supplied by that tube or tubule. Where the obturator is placed will be decided by the surgeon and will depend on the how localised the damaged region of lung is. That is to say, if the whole lobe is badly affected, then the obturator is placed in the lobar bronchus 22 supplying that lobe (as shown at 50 in Figure 1). On the other hand, if the damage is more localised, then the obturator will be placed in a smaller segmental bronchus 24, (as shown at 50' in Figure 1). Thus more than one obturator may be employed in the same pair of lungs isolating different regions of them. They will also be of different sizes, depending where they are to be inserted.

The above considerations equally apply when the condition being treated is not emphysema but some other condition which a doctor considers can usefully be treated by the method of the present invention. Such another condition is where a lung, or part of it is bleeding into the airway and an obturator isolates the bleeding region and inhibits coughing which may damage the lung further, or at least cause further discomfort to the patient.

Figure 2 shows an endo-bronchial obturator 50 complete with delivery device 70. The delivery device comprises a handle 72 and flexible guide tube 74. Slidably received in the guide tube is a delivery tube 76 having the obturator 50 disposed at its distal end 78. A release means 80 is insertable in a proximal end 82 of the delivery tube 76 and by means of which the obturator 50 may be ejected from the end of the delivery tube. The guide tube is guided down the trachea and into the appropriate bronchus by means of

guide lines (not shown) which enable the delivery system to be turned to follow the desired course. Optical guidance means may be included, or real-time X-ray or other monitoring methods may be employed to guide the surgeon. Once the end of the guide tube reaches the correct location, the delivery tube is inserted in the handle end of the delivery device 70, and then the release means 80 is pushed down the tube 76 to eject the obturator. The obturator is adapted to expand or be expanded, when ejected, to fill and block the tube or tubule in which it is inserted.

As can be seen from Figure 3a, the obturator 50a in its first embodiment is comprised of two main components, a securing element in the form of a stent 90, and a blocking element in the form of a closed-cell, PVC foam plug 92.

The stent 90 is constructed from a plurality of legs 91 of surgical grade stainless steel wire welded together such that when extended the stent appears as a series 90b of connected 'W's, as shown in an unconnected disposition in Figure 3c. Indeed, it is not essential that the final connection between ends 94,96 be made to form a closed crown arrangement (as shown in Figure 3a); it is equally effective merely to roll the stent 90b as indicated by arrows in Figure 3c.

When the two ends of the stent are joined together, the stent 90 folds into a circular frame or crown, capable of encompassing the biocompatible block 92. The stent is constructed so as to be of a size slightly smaller (in its unstressed condition) than the block, so that its natural resilience squeezes the block slightly. On the other hand, the stent should be larger than the airway into which it is to be introduced so that it presses outwardly against the wall of the airway, and is incorporated into the mucosa of the air passage.

The legs 91 of the stent crown are fitted with both internal barbs 98 and external anchors 100. The barbs 98 embed themselves in the block 92 and secure the block to the stent 90. The anchors 100 are adapted to engage the walls of the patient's airways to hold the stent in position.

Figure 4a shows an internal barb 98. The internal barb, also constructed from surgical quality stainless steel, is substantially straight and has a hook 99 at one end. The hooked end 99 is the point and means by which the barb is secured to the biocompatible block.

Figure 4b shows an external anchor 100. The anchor, which is also constructed from surgical quality stainless steel, is again substantially straight and has a coil 101 at its end. A coil is used so that damage is not caused to the tissue of the airway in which the obturator is fitted, particularly if and when the obturator is removed.

The barbs and anchors are joined to the stent crown by a welded joint between two adjacent legs 91. Barbs can alternate with anchors at the same end of the stent, or one end can have all barbs, while the other end has all anchors. Both arrangements are shown in Figures 3a and c respectively.

A different embodiment of obturator 50b, also in accordance with the present invention, is shown in Figure 3b in which surgical quality stainless steel wires are all welded together at a point 104 to form a domed stent 90bb. Legs 91b are alternately turned inwards to form barbs 98b, or outwards to form anchors 100b. Alternatively, all the legs could be anchors 100b, with interspersed shorter barbs 98bb, as one is shown in dashed lines in Figure 3b.

The aforementioned obturators all rely on resilience of the steel to return the stent to its original shape once

released from the delivery mechanism and so as to enable fitment in a narrower tubule than the unstressed size of the stent would otherwise allow. However, this requires prestressing the stent and keeping it stressed during delivery. Thus the present invention may find suitable application for memory metals, which only return to their original shape when some physical condition changes, for example, temperature rise or electrical current flow.

It is essential for the blocking device 92 to be comprised of a resiliently deformable material such as PVC foam as mentioned above. This enables the blocking device to be easily surrounded by the stent 90 and deformed into a compact structure, thereby enabling delivery of the block to its destination in the lung.

It is likewise essential that the block be capable of expanding and reforming into its original shape once deposited in the desired location in the lungs. It should be noted that the block is deformed and reformed in both an axial and a radial direction. It is the block 92 which seals a bronchial tube or tubule; mucous surrounds the block and forms a fluid tight seal. The presence of the stent around the block does not inhibit sealing in any way since the stent is essentially incorporated into the mucosa lining the airway.

Under compression, PVC foam has a high coefficient of friction which would prevent ejection from the delivery device as described above, if it was not surrounded by the stent 90, which offers a relatively low friction surface to the inside of delivery tube 76.

However, it is feasible that the block 92 could include a low friction surface to enable such ejection without the stent. Instead of the stent as described above, anchor means might be moulded in biocompatible plastics material as a crown, for example, on one end of the block, and

either be adhered, fused or otherwise bound thereto.

The effectiveness of the device depends, to some extent, on the length of the block. Moreover, the block is required to be of a size which is both comfortable to the patient once expanded in the lung and which expands to completely obstruct the passage of air into the affected portions of the lung. The extended size of the block therefore ranges between 5mm and 25mm in length, and between 5 and 11mm in diameter, depending on the size of the tube or tubule to be obturated.

Obturator 50c shown in Figure 5, comprises a balloon 200, which is inflated after insertion and then detached. The balloon is captivated in an appropriate securing device such as stent 202. In this case, the barbs would not be sharp, but would merely retain ends of the balloon, or, as shown, would comprise turned-in points 204,206 at each end of the stent. Anchors 201 are provided.

Finally, as mentioned above, the obturator may be as shown at 50d in Figure 6, where it comprises a diaphragm 300 expanded by an internal stent 302 having anchors 302. One end 306 of the diaphragm is attached to the stent to retain it on the stent. The diaphragm is also adhered to the stent.

While the obturator and method of the present invention has been described with reference to human patients, animal patients may in certain circumstances also benefit.

CLAIMS

1. Use of a blocking element (92,200,300) and a securing element (90,90b,90bb,202,302) in the manufacture of an obturator (50) for use in the treatment of a lung condition in a human or animal by blocking a bronchial tube or tubule.

2. Use of claim 1, in which the lung condition is emphysema.

3. Use as claimed in claim 1 or 2, in which the two elements are separate components, the blocking element serving to seal the tube or tubule against the passage of fluid past the obturator when the obturator is disposed in a bronchial tube or tubule, and the securing element serving to retain the blocking element in position in the tube or tubule.

4. Use as claimed in claim 1, 2 or 3, in which the blocking element comprises a substantially cylindrical plug of biocompatible material.

5. Use as claimed in claim 4, in which the plug comprises resiliently deformable closed-cell foamed plastics material, preferably PVC.

6. Use as claimed in any preceding claim, in which the securing element comprises a stent (90,90b,90bb,202,302).

7. Use as claimed in claim 6, in which the stent has barbs (99) to engage and retain the blocking element.

8. Use as claimed in claim 6 or 7, in which the stent has anchors (101) to retain the stent in a bronchial tube or tubule.

9. Use as claimed in claim 6, 7 or 8, in which the stent comprises a crown (90b) of surgical quality steel wire legs in zig-zag formation.

10. Use as claimed in claims 7, 8 and 9, in which said barbs and anchors depend from points of the crown.

11. Use as claimed in claim 9 or 10, in which the crown is closed in its circumference.

12. Use as claimed in claim 6, 7 or 8, in which the stent comprises a dome (90bb) of surgical quality steel wire legs (91b).

13. Use as claimed in claim 12, when dependent on claim 7, in which said barbs (98b) are formed on the ends of said legs.

14. Use as claimed in claim 12 or 13, when dependent on claim 8, in which said anchors (100b) are formed on the end of said legs.

15. Use as claimed in claim 1 or 2, in which the blocking and securing elements are integrally formed from plastics material, and wherein the securing element comprises adhered or fused anchor elements.

16. Use as claimed in claim 1 or 2, in which the securing element comprises a memory metal which is released to its normal expanded shape by a physical parameter when it has been inserted at the proposed location.

17. Use as claimed in claim 16, in which said physical parameter is the passage of electrical current through the securing means.

18. Use as claimed in claim 1, 2 or 3, in which the blocking element comprises a balloon (200).

19. Use as claimed in claim 18, in which the securing element comprises a stent (202), points (204) of the stent being turned inwardly to captivate the balloon.

20. Use as claimed in claim 1, 2 or 3, in which the blocking element comprises a diaphragm (300).

21. Use as claimed in claim 20, in which the securing element comprises a domed stent (302) secured at its point to the centre of the diaphragm, the legs of the stent pressing the diaphragm against the mucosa of a bronchial tube when inserted therein.

22. A method of treatment of emphysema or other lung conditions or diseases in human or animal patients, the method comprising placing an obturator in a bronchial tube or tubule of the patient so as to seal the tube or tubule against the passage of fluid past the obturator.

23. A method as claimed in claim 22, in which the obturator is put in place in a patient by use of a delivery device for the obturator, which device is inserted through the mouth and airway of the patient until the proposed placement site is reached, whereupon the device is activated to release the obturator from the device.

24. A method as claimed in claim 22 or 23, which method employs an obturator of the type manufactured in accordance with any of claims 1 to 21.

25. An obturator substantially as hereinbefore described with reference to any of the accompanying drawings.

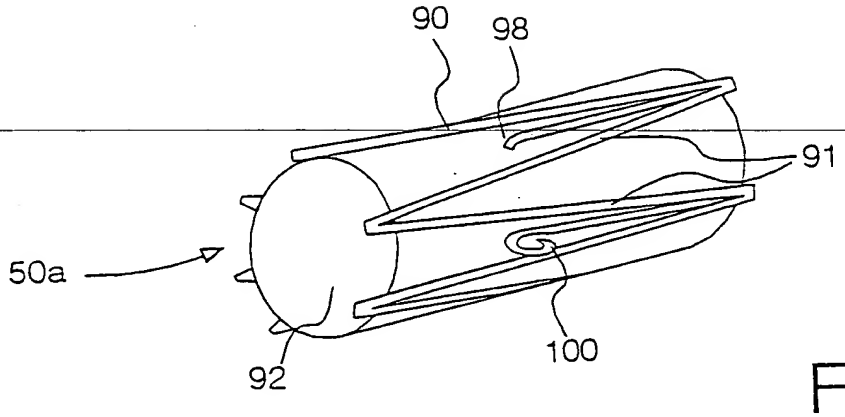

Fig. 3a

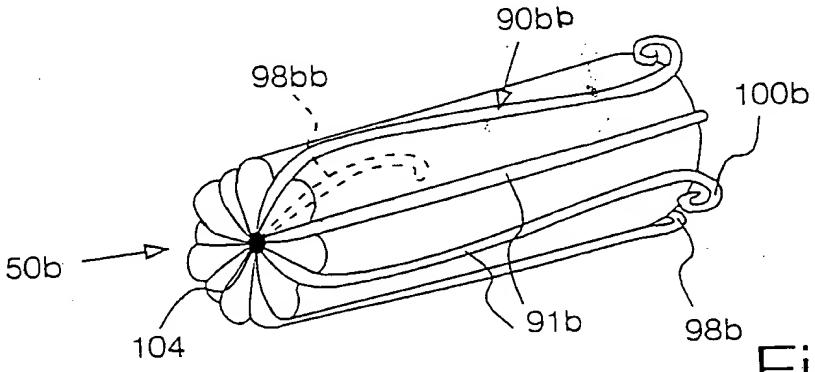

Fig. 3b

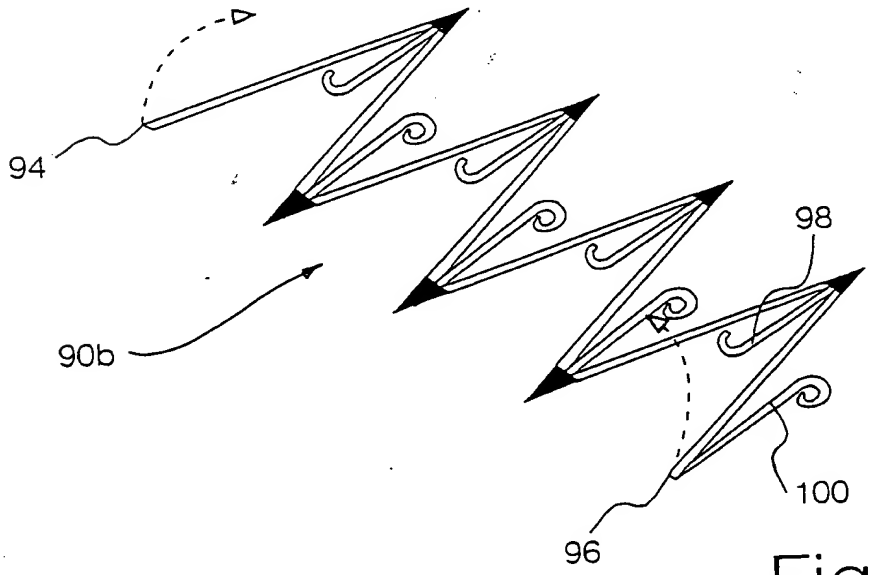

Fig. 3c

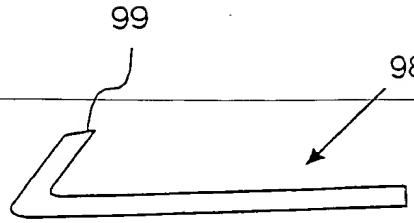

Fig. 4a

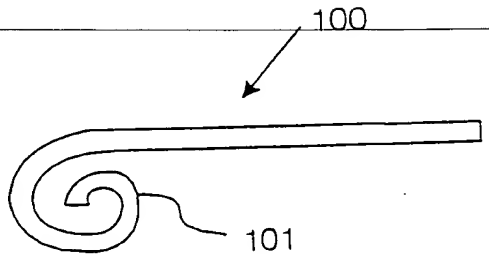

Fig. 4b

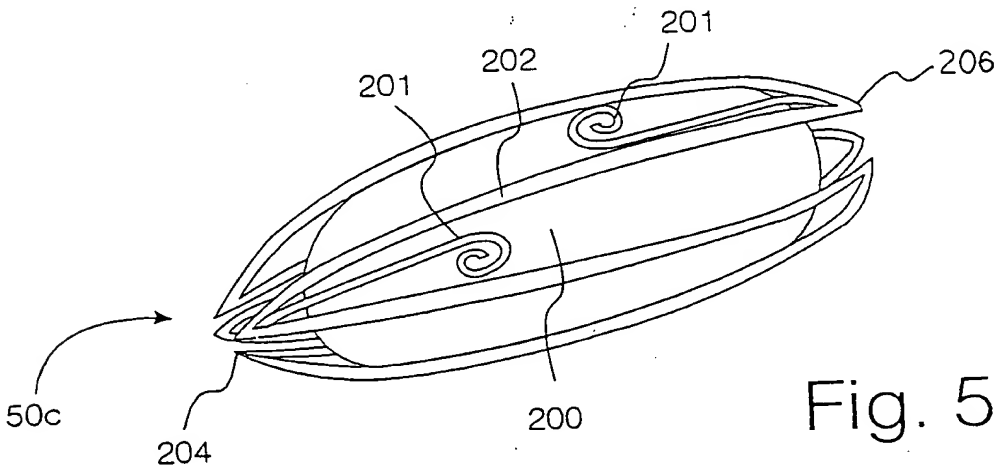

Fig. 5

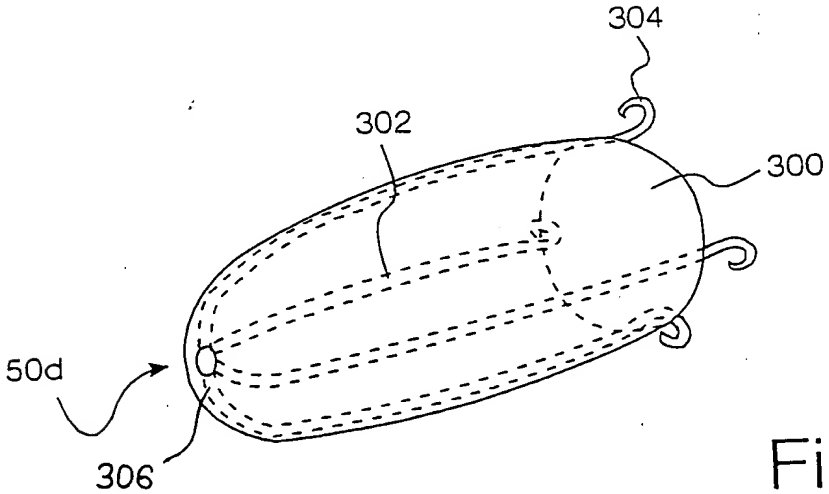

Fig. 6